D0MANUKU / GB

Owandy
DENTAL IMAGING SYSTEMS & SOFTWARE

Krystal-X Easy

INSTALLATION AND USER MANUAL

Version 24-02 – 24 July 2007

Index

1 INTRODUCTION 3

1.1 COMPLIANCE WITH STANDARDS 3
1.2 POWER SUPPLY 4
1.3 INSTALLATION PRECAUTIONS 4
1.4 LIABILITY AND OPERATORS 4
1.5 PACKAGING AND ENVIRONMENT 5
1.6 MARKING AND LABELLING SYMBOLS 5

2 CONTENTS 6

3 INSTALLATION 7

3.1 PRECAUTIONS 7
3.2 EQUIPMENT INSTALLATION 8
3.3 SOFTWARE INSTALLATION 11
3.4 CONFIGURATION IN THE OWANDY IMAGING SOFTWARE 14
3.5 SHARING THE SENSOR AND BOX BETWEEN DIFFERENT WORKSTATIONS 15

4 USE 16

4.1 PRECAUTIONS 16
4.2 LIGHTS AND BUTTON ON THE BOX 16
4.3 USE OF THE OWANDY XIO STANDALONE SOFTWARE 17
4.4 ACQUISITION OF AN IMAGE 19
4.5 EXPOSURE TIME 20

5 HYGIENE AND MAINTENANCE 21

5.1 HYGIENE AND DISINFECTION 21
5.2 RECOMMENDED DISINFECTION PROCEDURE 22
5.3 MAINTENANCE 22

6 TROUBLESHOOTING 23

6.1 GENERAL 23
6.2 IMAGE QUALITY 24

7 SPECIFICATIONS 25

8 OPTIONAL KITS AND ACCESSORIES 26

8.1 OPTIONAL KITS 26
8.2 ACCESSORIES 26

The manufacturer, Owandy S.A.S., reserves the right to make modifications to its products or to their specifications in order to improve the performance, quality, or ease of production. Specifications of products or accessories may be modified without prior notice.

No part of this manual may be reproduced without the prior consent of the manufacturer, Owandy S.A.S.

Language of original document: French.

OWANDY SA
6 Allée Kepler
F-77420 Champs sur Marne
France
Telephone : +33 1.64.11.18.18
Fax : +33 1.64.11.18.10

CE 0459

1 Introduction

You have just received your Krystal-X Easy digital intra-oral radiology kit. We thank you for the confidence you have in us and hope that this product will give you entire satisfaction.

We recommend you to read this manual thoroughly before installation; following the guidelines for installation and usage described in it will exclude risks to the patient and the care team. Please keep it close to your equipment so you can refer to it at a later date.

Your sensor uses an X-ray sensitive electronic detector (the flat part at the bottom of the sensor) that replaces the conventional film used for the acquisition of radiological intra-oral images. The X-rays are automatically detected by the sensor which triggers image acquisition. The acquired image is displayed almost instantaneously on the screen of the computer to which the sensor is connected. These digital images can then be manipulated, analysed, saved as files or printed.

The development process of conventional films is thus completely eliminated as well as the possible influences on image quality; such as the type and age of the chemical product, the temperature of the baths or the development time.

The sensor is available in two sizes; depending on the kit you have ordered you received a size 1, a size 2 sensor or both:

- The size 1 sensor allows you to acquire the majority of intra-oral images (peri-apical and retro-coronary) both vertically and horizontally.
- The size 2 sensor furthermore allows you to easily acquire horizontal “bitewing” images.

The instructions and information in this manual refer to both sensor sizes, unless specifically stated. The size of the sensor is marked on the sensor itself.

1.1 Compliance with standards

The Krystal-X sensor is class IIA equipment within the meaning of the European Directive concerning CE markings, annexe IX of book Vbis of the Public Health code, supplementing Directive 93/42/CEE of the 14th of June 1993. The sensor complies with medical standard EN/IEC60601-1. The Krystal-X Easy kit complies with directive 93/42 CE (annexe VII) of decree 95-292 of the Public Health code.

Under certain conditions (see “1.3 Installation precautions”) it is necessary that the other components of the system that are possibly connected (computer and optional peripherals) are also compliant to standard IEC950 (EN60-950) and that the installation complies with directive 93/42 CE.

The intra-oral sensor is contained within a hermetic case, sealed in compliance with standard IPX7.

The secondary electrical insulation of the sensor is determined by the materials used.

There is no physical or electrical connection between the Krystal-X Easy kit and the X-ray generator.

1.2 Power supply

The power to the Krystal-X Easy box is provided directly by the power supply of the USB cable.

1.3 Installation precautions

Regulation requires that your computer is at least compliant with standard IEC950 (EN60-950) if it is not within the patient environment.

1.3.1 Installation of the box outside the patient environment

The Krystal-X Easy kit has been developed so that the box is positioned outside the patient environment when in use; meaning at a distance of at least 1,5m / 4.9ft of the patient (measured horizontally) or at more than 2,5m / 8.2ft of the ground (measured vertically) if the horizontal distance is not complied with.

1.3.2 Installation of the box within the patient environment

If the computer or the box are situated inside the patient environment (less than 1,5m / 4.9ft from the patient), your computer must necessarily comply with standard EN/IEC60601-1, or your installation including the computer must have been rendered compliant with standard EN/IEC60601-1-1. You can connect the box to your computer without additional precautions once your complete installation is compliant with standard EN/IEC60601-1-1.

If the computer is not situated in the patient environment and is not compliant with standard EN/IEC60601-1, it is necessary to apply appropriate installation precautions to make sure the box is inaccessible to the patient (when the box is installed inside the dental chair) or to place the box in non-conductive packaging.

1.4 Liability and operators

Installer: the installation of the kit requires computer skills relating to both equipment and software. Follow the recommendations and guidelines of the installation chapter to install the equipment and software.
User: the kit must be used by a dental practitioner.

The connection box should never be opened by the user. Only the manufacturer is authorised to open and make repairs to the sensor or box. Return the equipment to the distributor in case of malfunction and/or if the documentation you possess does not contain the necessary information for the (authorised) maintenance of the malfunctioning equipment.

The manufacturer will not be liable if:

- Interventions or repairs have been made by persons without the authorization of the manufacturer or distributor and are not part of accepted interventions.
- The equipment is used with an installation that is not compliant with the applicable standards and decrees - in particular when not compliant with the EN/IEC60601-1-1 standard relating to the security rules for electro medical systems. Make sure the installation of the equipment is compliant with the applicable regulations.
- Used in ways other than those mentioned specifically in this manual (use of the kit in normal conditions of use and in compliance with its intended purpose).

1.5 Packaging and environment

Transport, storage and environment: the kit is supplied in protective packaging (protection against physical impacts and antistatic packaging). It must be stored under the following conditions:

Ambient temperature:	-10°C to +70°C / 14°F to 158°F
Relative humidity:	10% to 100%
Atmospheric pressure:	500hPa to 1060hPa

Operation: in compliance with the international safety standard EN/IEC601-1 (section 2), the kit has been designed for normal use under the following conditions:

Ambient temperature:	+10°C to +40°C / 50°F to 104°F
Relative humidity:	30% to 75%
Atmospheric pressure:	700hPa to 1060hPa

Equipment packaging for return to distributor: should a return to the distributor be necessary, make sure to package the sensor and box kit in its original packaging after having cleaned it thoroughly.

Documentation loss: all kits are shipped with its documentation. Please contact your distributor for a replacement manual if this documentation is lost.

1.6 Marking and labelling symbols

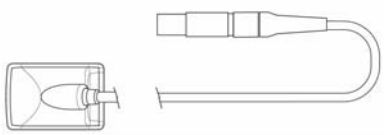
These symbols are used on the product labels and inform you about the compliance with standards and the technical specifications of the component.

⎓	Direct current.		Type BF equipment, EN/IEC 60-601-1, annexes I and II.
	Sealing standard of the sensor, regulation EN/IEC 60529. **Only the part of the sensor that is inserted in the mouth complies with this standard.**		Important information: follow the instructions printed in this manual.
CE 0459	The CE marking certifies that this product complies with European directive 93/42 CEE.		Class II device within the meaning of standard NF EN/IEC 60601-1-1 (reinforced or double insulation).
	Equipment subject to a selective collection in accordance with Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) and with Decree 2005-829 of the 20th July 2005 regarding the composition of electrical and electronic equipment and the elimination of waste coming from this equipment.		

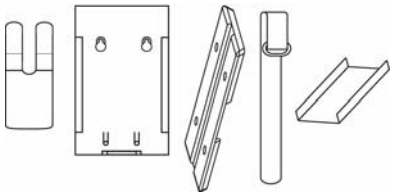
2 Contents

Your Krystal-X Easy kit consists of the following elements (illustrations may vary from items supplied):

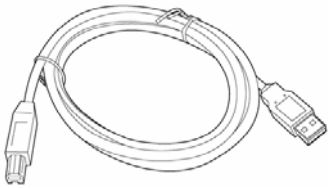
A Krystal-X Easy box
(compatible with Krystal-X size 1 or 2 sensors)



A Krystal-X sensor
(size 1 or size 2)
(cable of 80cm or 2,95m / 2.6ft or 9.7ft)



1 sensor wall support
1 box wall support (with 2 screws, 2 plugs)
1 box base plate (with 4 self-tapping screws,
4 transparent plastic feet, 1 strap)
1 box adaptor for sensor size 2 > size 1



A USB 2.0 cable (3m / 9.8ft)

An introductory pack of positioners
(size 1 or 2 depending on your sensor)

A bag of disposable single-use hygienic protective sleeves (for size 1 and 2 sensors)

An O.S.P. installation CD-ROM
(drivers/diagnostic tools)
A CD-ROM with the installation files of the sensor

A manual
A packaging checklist

3 Installation

3.1 Precautions

The kit must be handled with care, minimise the twisting, pulling and bending of the attachment cable. Do not step or roll on the cable. Do not pull on the cable itself but on the connection plug to disconnect the attachment cable.

To avoid interferences in the image, do not use the system close to strong magnetic fields and avoid proximity to electrostatic emission sources.

Read paragraph “1.3 Installation precautions” to ensure the installation complies with the standards.

Install your imaging software before the installation of the kit, its drivers and O.S.P. tools and the installation files of the sensor.

3.1.1 Recommended minimal configuration

Any computer configuration that does not comply with the minimal recommended configuration can prevent the starting or proper functioning of the sensor kit. Verify the specifications of the computer(s) before the installation.

Operating system	Vista, Windows XP service pack 1, Millennium or 98 second edition
Computer Motherboard USB port	Compliant CE-IEC950 Intel 1.2GHz chipset and processor Compatible USB 1.1; USB 2.0 High-Speed recommended
Graphics card Monitor	64MB High resolution 1024x768 (15inch)
RAM memory Hard disk	256MB 10GB
CD-ROM drive Backup system	24x External/removable disk, Zip or Jaz system, CD-ROM/DVD…
Printer Keyboard and mouse	Laser, inkjet, thermal
At acquisition workstation	Krystal-X Easy kit with appropriate drivers Imaging software X-ray generator with electronic timer

If your computer does not possess USB 2.0 ports, these can be added as PCI cards (for desktop computers) or PCMCIA cards (for laptops). If the USB ports do not provide enough current, please use a powered hub (with its own power supply). The PCMCIA cards need to be powered by an external power supply or connected to a powered hub if they do not provide enough current. Please contact your IT specialist for further information.

3.1.2 Setup guidelines

The computer and the screen with which the sensor and the box are used should preferably be situated close to the chair, within the field of vision of the practitioner, to allow for immediate use. Provide visual access for the patient to be able to share the radiological information with him/her.

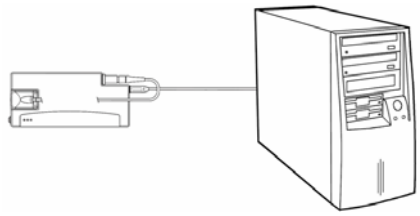
The screen must be place so as to avoid any reflections or direct overhead illuminations that could be detrimental to the visualization of the radiological images. It must be set up (contrast and brightness) to display as many grey levels as possible in the image.

The X-ray generator has a great influence on the quality of the acquired images. The kit is compatible with any kind of generator, be it high-frequency or conventional. The generator must be equipped with an electronic timer (allowing for very short exposure times) and must emit a dose sufficient for the acquisition of a good image (with enough grey levels). Make sure that your generator is not worn as the dose emitted will be insufficient and could influence the quality of the acquired image. The energy emitted by a generator diminishes over time; when in doubt have your generator checked by a qualified technician. Make sure he had of the generator is stable, any movement of the head will induce movement blur in the acquired image.

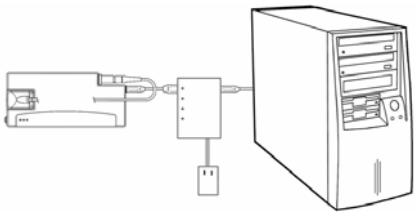
3.2 Equipment installation

3.2.1 Connections

The Krystal-X Easy box provides connectors for the sensor and the USB cable linking it to the computer. It must be connected to the computer using the USB 2.0 cable provided with the kit. If the distance between the box and the computer is greater than the 3m / 9.8ft of USB cable provided with the kit, it is possible to add USB cables by using powered USB hubs between each cable.

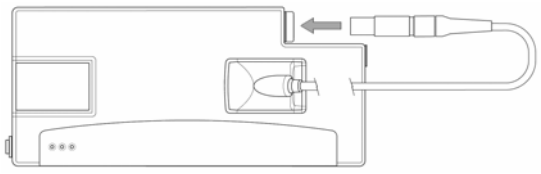


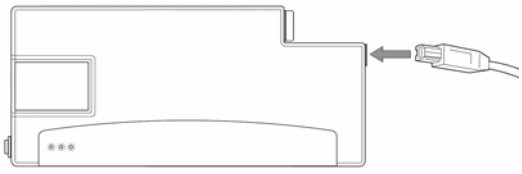
Connection without hub



Connection with powered hub

Connect the sensor cable connector to the box by aligning the red dot on the plug with the red dot on the socket of the box – do not try to force the insertion of the plug, it could damage the connector. The Krystal-X Easy box accepts size 1 or 2 Krystal-X sensors.





Make sure the USB port of the computer is preferably a USB 2.0 port. Only use USB 2.0 cables and hubs with a USB 2.0 port and make sure that the hub has its own external power supply (do not use self-powered hubs, drawing the power from the USB cable). Each USB cable should not be longer than 3m / 9.8ft. The kit is compatible with USB 1.1 ports but with reduced image transmission speed.

Do not connect or disconnect the sensor waiting for an acquisition or during an acquisition, you could damage the sensor. Make sure the box is in standby mode before disconnecting the sensor. The USB cable can be connected / disconnected without the need to power down the computer.

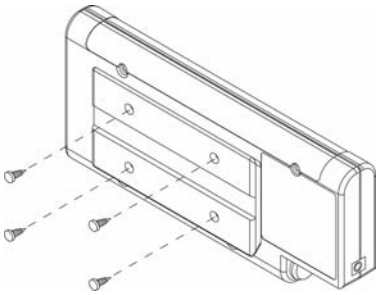
Check that the box is correctly connected: switch it on with the button; if the green light on the box is switched on, it is powered correctly.

3.2.2 Box and sensor supports

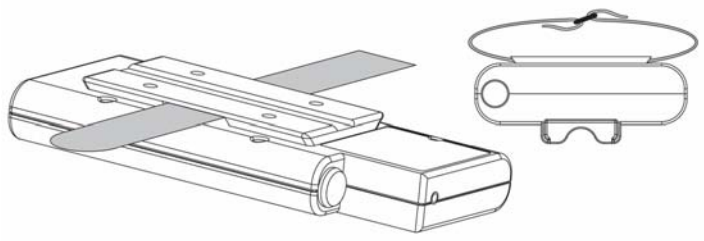
The box can be mounted or placed on different supports using the accessories provided with the box.

Place the box on a worktop: stick the non-slip feet provided with the kit to the back of the box if you want to place the box on a worktop.

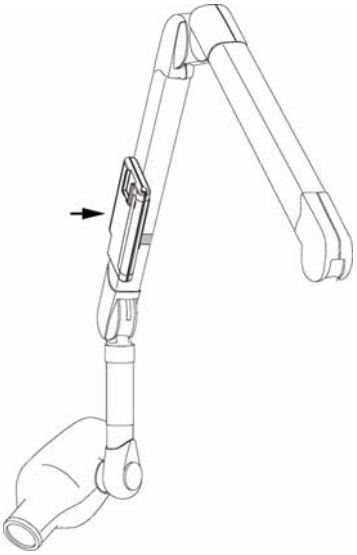
Attach the box with the strap: if you want to use the strap to position the box, attach the base plate of the wall support to the back of the box using the 4 self-tapping screws (use only the screws provided with the kit or you could damage the box).

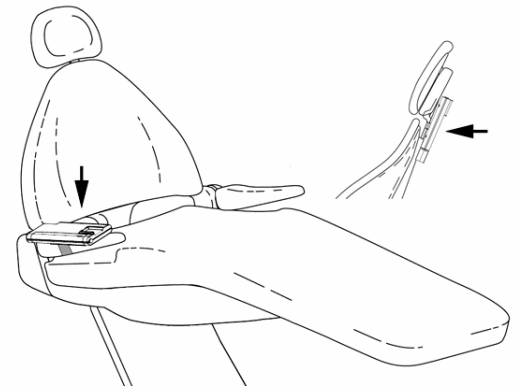


Pass the strap under the base plate (as indicated in the drawing underneath) and close it on itself to ensure the Velcro fastening holds.

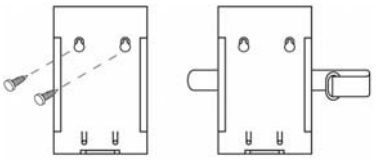


Your box can now be attached to a support with the strap, e.g. to the arm of your X-ray generator, to the headrest or armrest of your chair.



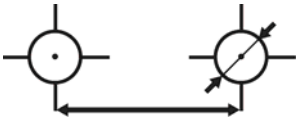


Mount the box using the wall support: it is also possible to insert the box with the base plate in the wall support of the box.

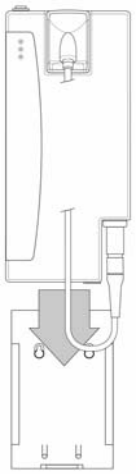


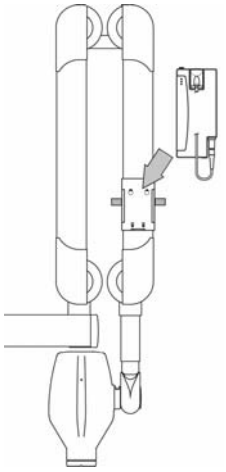
The wall support can be mounted on a wall, a worktop or object either by using the screws or by using the strap, passing it through the slits provided for that purpose in the wall support of the box.

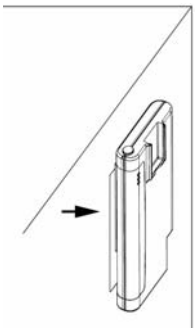
To mount the wall support of the box, drill 2 holes according to the outline opposite. Insert the plugs, screw in the screws and hook on the wall support to these attachments. Slide the box in the wall support using the base plate.



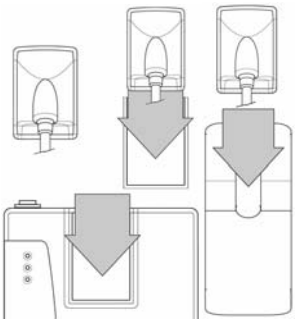
Do not mount the wall support of the box upside-down or horizontally, the box and sensor could fall on the ground and be damaged.



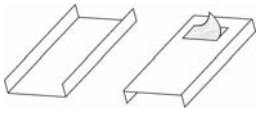




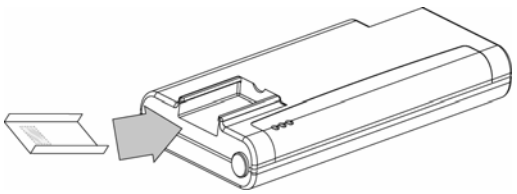
Storing the sensor: it is possible to store the sensor in the space provided in the box.

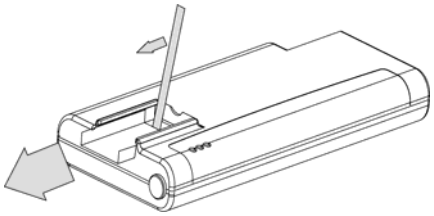


An adapter is included to store the size 1 sensors in the box's storage area. Remove the protective film from the double sided adhesive at the back of the adapter before inserting it in the sensor storage space. The part of the adapter with the adhesive must be inserted last, this to allow you to remove the adapter at a later date. The adapter can be removed by applying a lever on the inserted adapter and the side of the compartment to detach the adapter and eject it.



The kit is also provided with a wall support for the sensor; this support is compatible with size 1 and 2 sensors and can be mounted to a wall, a worktop or to equipment. It allows you to store the sensor within easy reach and to protect it against eventual impacts or drops.





3.3 Software installation

Install the Owandy QuickVision (or third party) imaging software and check its proper functioning before installing the equipment and its drivers. Refer to the software manual for the installation instructions.

You need administrator rights for the installation and use of the software and equipment. Please contact your IT specialist to create a suitable user account.

3.3.1 Installation of the drivers

Automatic installation for Windows 98SE and Millennium: after having connected the box to the USB port of the computer, Windows will detect automatically the new equipment and ask for the corresponding drivers.

1. Insert the O.S.P. CD-ROM and click on the “Next” button in the window “Add new hardware” that is displayed on-screen.
2. Check the box “Search for the best driver for your device” and click on “Next”.
3. In the new window, do not check the box “Search for location” and click on “Browse”.
4. On the CD-ROM, navigate to the “\drivers\WIN_98_ME\Owandy USB” directory in the navigation window that appears and click on “OK”.
5. Windows will indicate is has found the drivers for the “Krystal-X Easy”; click on “Next” to start the installation.
6. Click on “Exit” in the last window of the wizard to finalise the installation.

7. To start the installation of the O.S.P. tools please refer to paragraph “3.3.2 Installation of the O.S.P.”.

The “Krystal-X Easy” is installed under “Universal Serial Bus controllers” in the “Device manager”. To reach this window click on the Workstation icon with the right mouse button and select “Properties”, then “Device manager”.

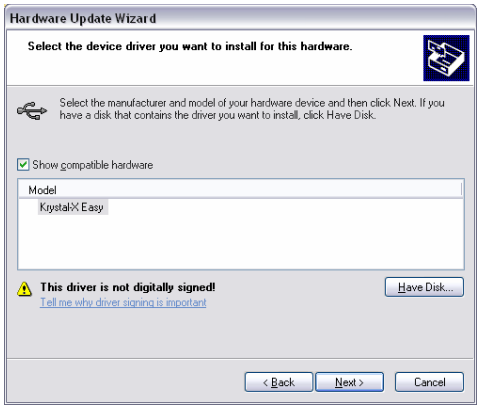
Automatic installation for Windows 2000, XP and Vista: insert the O.S.P. CD-ROM in the CD-ROM-drive. The interface will launch automatically and will guide you through the different installation steps. Refer to the Windows help if the CD-Rom does not automatically launch.

1. Select the desired language in the main screen. The tabs at the top of the page link to different pages of the Owandy website and provide more information regarding Owandy.
2. Click on “Install”, then on “Next”.
3. Select “USB” in the menu that appears.
4. Connect the USB cable to the connection box and the USB 2.0 port of the computer. Windows will automatically detect your box.
5. Cancel the window “Add hardware wizard” that appears then click on “Click here” in the window of the O.S.P. installer.
6. In the new window, confirm the location of the drivers that is displayed by clicking on “Install”. This location must correspond to the directory of the drivers on the O.S.P. CD-ROM. The driver files are then copied to your hard disk.
7. Click on “Continue” in the message window “Equipment installation” that appears.
8. A confirmation window is displayed after the files have been copied, it confirms the drivers have been installed correctly by displaying “Krystal-X Easy: Installed”. Click on “OK” to close this window.
9. After the installation of the drivers click on “Next” in the main O.S.P. window.

10. Select “USB X-Ray” to start the installation of the O.S.P. tools. Refer to paragraph “3.3.2 Installation of the O.S.P.” for installation instructions.

Manual installation: it is also possible to install the drivers manually by using the "New hardware detected assistant" of Windows. Follow these steps:

1. Connect the connection box to the USB 2.0 port of the computer. Windows will automatically detect your equipment and will display the "Found New Hardware Wizard" window.
2. If the wizard requests the authorization to connect to the Windows Update site, select "No, not this time", then click on "Next". This window does not appear depending on your version of Windows.
3. The wizard will inform you it has detected your "Krystal-X Easy" kit. Select "Install from a list or specific location" then click on "Next" after making sure the O.S.P. CD-ROM is inserted in the CD-ROM drive.
4. Select "Don't search. I will choose the driver to install" and click on "Next".
5. Click on "Have Disk" under the list that is displayed. If the window containing this list does not appear, click on "Show All Devices" then click on the "Have Disk" button.
6. The next window will allow you to navigate to the directory that contains the required files; click on "Browse".
7. Navigate to the "\drivers\WIN_2000_XP\OWandy USB" directory on the O.S.P. CD-ROM; this directory contains the file "ow_usb.inf". Click on "OK" to select this directory.
8. The previous window now displays the location of the files to be installed: "E:\drivers\WIN_2000_XP\OWandy USB" (E : representing the letter of your CD-ROM drive, this can be different depending on your computer configuration). Click on "OK" to start the installation.
9. The "Krystal-X Easy" drivers are displayed in the list (see opposite); click on "Next".
10. Click on "Continue" in the warning window "Device installation" that appears.
11. Finally click on "Exit" in the last window of the wizard.


Hardware Update Wizard
Select the device driver you want to install for this hardware.
Select the manufacturer and model of your hardware device and then click Next. If you have a disk that contains the driver you want to install, click Have Disk.
Show compatible hardware
Model
Krystal-X Easy
This driver is not digitally signed!
Tell me why driver signing is important
Have Disk...
< Back
Next >
Cancel

The "Krystal-X Easy" is installed under "Universal Serial Bus controllers" in the "Device manager". To reach this window click on the Workstation icon with the right mouse button and select "Manage" in the drop-down menu. In the window that appears select "Device manager".

3.3.2 Installation of the O.S.P.

Automatic installation for Windows 2000, XP and Vista: the installation of the O.S.P. tools is automatically proposed after the installation of the drivers. Refer to the procedure below.

Automatic installation for Windows 98SE and Millennium: insert the O.S.P. CD-ROM in the CD-ROM-drive. The interface will launch automatically, click on the button and follow the installation procedure below. Refer to the Windows help if the CD-Rom does not automatically launch.

1. Select the desired language in the window that appears and click on "Next".
2. In the welcome screen click on "Next".
3. Select the target directory (the directory where the software will be installed) by clicking on "Browse" and by navigating to the desired directory. If you use the QuickVision imaging software select the directory where you installed QuickVision (proposed by default). After having selected the target directory click on "Next".
4. Click on "Install" to start the copying the files.
5. After the files have been copied, select "Krystal-X Easy V1" in the list that appears and click on "OK".
6. A window will inform you of the successful installation, close it by clicking on "Exit".

7. The last window displays the location of the O.S.P. tools; close this window by clicking on the red cross of the window (top right).
8. Close the main O.S.P. installation window if it is still displayed on-screen.

Manual installation: if you have followed the manual installation of the drivers or you are installing under Windows 98 or Millennium, you must start the manual installation of the O.S.P. tools:

1. Insert the O.S.P. CD-ROM in the CD-ROM drive.
2. Navigate to the "\setups\USB_XRAYS_BOX_W98_WME_W2000_WXP" directory on the O.S.P. CD-ROM.
3. Launch "setup.exe".
4. Click on "USB X-Ray" to start the installation of the O.S.P. tools. Refer to the automatic installation of the O.S.P. mentioned above.

3.3.3 Sensor installation files

Each kit is provided with a sensor installation CD-ROM of its own; the serial number of the sensor is written on the CD-ROM. You can therefore not use the same CD-ROM to install several kits.

Before installing the sensor installation files, make sure that:

- The drivers of the kit are installed.
- The imaging software is not started.

Insert the sensor installation CD-ROM, a window appears and the files are copied to the hard disk. Close the window after the files have been copied by pushing any key of the keyboard when asked for.

3.3.4 O.S.P. update

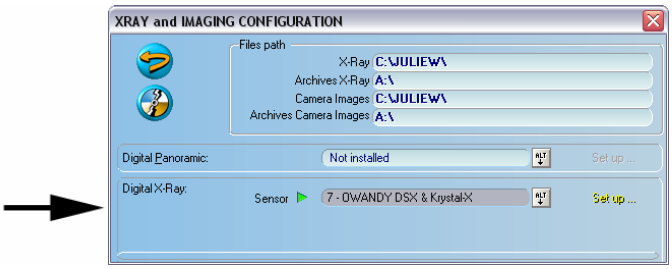
If you need to update your O.S.P.:

1. Insert the O.S.P. CD-ROM.
2. Navigate to the "\setups\USB_XRAYS_BOX_W98_WME_W2000_WXP" directory on the CD-ROM.
3. Launch "setup.exe".
4. Click on "Install or Reinstall" and be guided by the instructions on-screen.

3.4 Configuration in the Owandy imaging software

To be able to use your kit with the Owandy QuickVision imaging software you must configure your equipment:

1. Start the imaging software (double-click on the desktop icon or use the link in Start / Programs / QuickVision).
2. Click on the “Configuration” button in the main screen.
3. Select “OWANDY DSX & Krystal-X” under the “Intra-Oral sensor” option in the window that appears.



4. Click on “Configure” at the right of the menu.

In the configuration window:

◄ Check the “USB” model.

◄ Select the “Krystal-X Easy - 520” kit.

◄ Set the activation time of the box (default 5min).

◄ Select the image treatment (*).

◄ Configure the Owandy software (**).

(*) When the “Film alike” option is activated, the contrast depends on the exposure time. Adjust the X-ray dose on the generator to obtain a good image.
(*) When you select the option “Auto contrast” the contrast is constant. Exposure errors are corrected automatically, which reveals noise in badly exposed images.

In both cases, the exposure bar (blue/green/red) helps to find the correct exposure of the images.

(**) This option appears only when the sensor is used from certain Owandy software programs; it allows the change of the sharpness setting or the high resolution for each acquired image.

5. Click on “OK” to confirm your choice.
6. Then click on the “Save” button to validate the settings.

The use of the kit is identical to the use of the Owandy XIO StandAlone software described below.

3.5 Sharing the sensor and box between different workstations

Sharing the sensor and the box allows you to use one or more sensors in turn in a practice with multiple chairs. It is recommended to link the different workstations in a network to allow for the central storage and sharing of the images. A USB cable must be plugged into each workstation for fast connection of the box. Windows will automatically recognise the equipment when it is connected and it will be available immediately for image acquisition.

To enable the sharing of a kit between different workstations, it is necessary to first install the imaging software for the acquisition of the images, the drivers, O.S.P. tools and sensor installation files on all the computers to which the box will have to be connected.

4 Use

4.1 Precautions

Make sure the sensitive surface (the flat surface) of the sensor is directed towards the X-ray generator. The active surface of the sensor is marked by a frame. The back of the sensor (rounded) does not react to X-rays and does not produce an image on-screen.

The kit must be manipulated with care, minimising the twisting, pulling and bending of the attachment cable. Do not step or roll on the cable. Be careful not to pull on the cable when removing the hygienic protective sheaths.

Do not pull on the cable itself but on the plug to disconnect the attachment cable. Do not connect or disconnect the sensor waiting for an acquisition or during an acquisition, make sure the box is in standby mode before disconnecting the sensor.

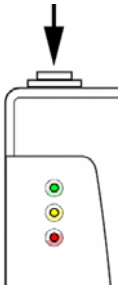
Even though the sensor is resistant to impacts, it is strongly recommended to not let it fall on the floor. If a physical impact should exceptionally happen, contact your distributor and do not try to intervene yourself.

Do not ask the patient to bite on the sensor or cable.

4.2 Lights and button on the box

During initialisation of the box, the green and yellow lights light up; once the initialisation finished, only the green light remains lit.

The box automatically switches to standby mode after a period that can be set in the configuration window (see below - the default period is 5 minutes). All lights are off when the box is in standby mode and the sensor toolbar turns red. To reactivate the box you only need to push the button on the box.



The lights inform the user about the state of the box:

- Green light only: sensor ready for image acquisition.
- Yellow light: sensor not available (in preparation or transmitting).
- Red light only: an error occurred, restart the box.

4.3 Use of the Owandy XIO StandAlone software

4.3.1 Modes of operation

The sensor kit can function in two ways:

- Through the **Twain protocol** (for scanners): to use this mode select “Owandy USB Intra Oral Twain drivers” in the TWAIN acquisition option of your imaging software. Subsequently start the TWAIN acquisition; the interface is identical to that of the independent mode described below.

- In **independent mode**: the independent software program can be started with the icon (on the Windows desktop) or by starting an Owandy software program. This memory resident software package allows the use of the sensor outside any software program. If an image is acquired without a program ready to receive it, the resident program will display the image on-screen for a few seconds and save it in the “C:\Program Files\OWandy\OSP - USB XRAYS BOX\standalone\Data” directory on the hard disk. A sensor icon appears in the Windows taskbar, next to the clock. The colour of the icon indicates the state of the sensor:

	Red: sensor inactive
	Yellow: sensor initialising
	Green: sensor ready for acquisition

4.3.2 Sensor toolbar

It is possible to display the sensor toolbar by clicking with the right mouse button on the sensor icon in the taskbar. The colour of the sensor toolbar indicates the state of the sensor:

	Red: sensor inactive
	Yellow: sensor initialising
	Green: sensor ready for acquisition

Options of the sensor toolbar:

◄ Orientation of the sensor (vertical or horizontal),
double-click on the icon to change the orientation of the sensor.

◄ Activate/deactivate the sensor.
◄ Extension/reduction of the toolbar to hide/display the options.

◄ Configuration of the resolution: check the option to acquire images in full resolution; uncheck the option to switch to standard resolution.

◄ Iconize the toolbar in the taskbar.

The resolution and operation mode can only be modified when the green light of the box is on. The box needs a few seconds to change the parameters.

The box automatically switches to standby mode after a few minutes of not being used; the lights will switch off and the sensor toolbar turns red. Push the button on the box to restart the kit.

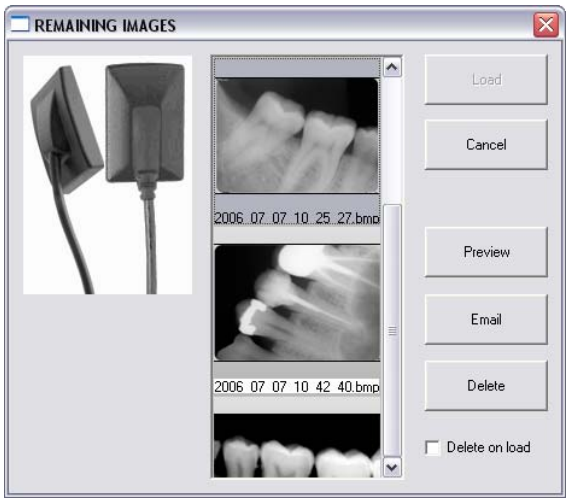
Check the state of the lights on the box and the colour of the sensor toolbar before each acquisition: the green light must be switched on and the toolbar must be displayed in green.

4.3.3 Configuration menu

A right-click on the sensor icon in the taskbar or on the sensor toolbar displays the configuration menu:

X-ray sensor	Displays the sensor toolbar.
Start when Windows starts	Once checked, the StandAlone program will be launched each time your computer is started.
Configuration	Displays the configuration menu (see “3.4 Configuration in the Owandy imaging software”).
Display new image during	Adjusts the display time of the image.
Remaining images	Allows you to browse through the images waiting to be transferred. If no image is acquired this option is not displayed.
Exit	Closes the resident software program. **Warning**: the acquisition will no longer be available until the resident program is restarted.

4.3.4 Image transfer interface



Options of the image transfer interface:

Image display	When an image is selected, it is displayed on a blue background.
“Load” button	Transfers the selected image to the software program.
“Cancel” button	Cancels the image selection and starts the toolbar for a new acquisition (only when in a software program).
“Preview” button	Displays the selected image full-screen.
“Email” button	Opens a blank email and attaches the image in a zip file.
“Delete” button	Deletes the selected image.
“Delete on load” option	Deletes the selected image from the list after it has been transferred to a software program.

4.4 Acquisition of an image

4.4.1 Acquisition procedure

The image acquisition goes through several steps:

1. Before being able to acquire an image with the sensor, you need to start the computer with which the box will be used and start the imaging software. Check that the sensor toolbar or the sensor icon is green and that the green light on the box is lit and the yellow light is not lit.

2. Program the different parameters (exposure time, etc.) on the X-ray generator (see “4.5 Exposure time” for more information).

3. Cover the sensor with a hygienic protective sheath making sure to cover a sufficient length of cable.

4. A set of positioners is provided with the kit to place the sensor in the different parts of the mouth; their use is recommended to ensure the sensor is positioned perpendicularly to the X-ray beam.

   The sensor can also be positioned manually, maintained by the patient as with conventional film. This can be necessary for children with a small oral cavity. Position the sensor in the mouth, behind the tooth of which you want to acquire an image. If you do not use a positioner, a cotton roll can be helpful to position the sensor parallel to the tooth.

   Turn the sensitive surface of the sensor (the flat surface) towards the generator; if it is facing the other way, the sensor will not be able to acquire images.

   Refer to the poster provided with the positioners for more information regarding the positioning for anterior, posterior, endo and bitewing images.

5. Position the generator so as to cover the whole sensitive area of the sensor. The paralleling technique is strongly recommended and the use of positioners allows you to correctly place the generator thanks to the aiming ring.

6. Activate the generator. The green and yellow lights of the box will light up to indicate the treatment of the acquired image. Once the image treated, it appears in the imaging software and the green light of the box lights up allowing a new acquisition.

4.4.2 Owandy imaging software functions

This function is available only to users of the Owandy imaging software.

When the image is displayed in the Owandy QuickVision imaging software, a coloured bar appears in the top part of the image, this is the exposure bar.

The white cursor displayed in this bar indicates the exposure level of the image:

- If the cursor is in the green, the image is correctly exposed.
- If the cursor is in the red, the image is over-exposed; reduce the exposure time on the generator.
- If the cursor is in the blue, the image is under-exposed; increase the exposure time on the generator.

4.4.3 Third party imaging software functions

If you do not possess the Owandy imaging software, an exposure percentage is displayed in the acquired image:

- 0 to 80% - under-exposed image, the X-ray dose is too low; increase the X-ray dose on the generator.
- 80 to 120% - correctly exposed image
- 120 to 200% - over-exposed image, the X-ray dose is too high; reduce the X-ray dose on the generator.

4.5 Exposure time

Recommended exposure times in seconds for the Owandy X-ray generators:

Description	Owandy Altis DC	Owandy Elios AC
Current / Voltage	**4mA / 65KV**	**8mA / 70KV**
Lower incisor / canine	0.06 – 0.10	0.02 – 0.06
Lower premolar	0.06 – 0.10	0.04 – 0.08
Lower molar	0.10 – 0.14	0.08 – 0.12
Upper incisor / canine	0.06 – 0.10	0.04 – 0.08
Upper premolar	0.08 – 0.12	0.06 – 0.10
Upper molar	0.10 – 0.14	0.08 – 0.12

Reference conditions:

- *Adult patient, young man or woman of average size*
- *Distance focal spot to sensor 250mm / 9.8inch*
- *Total (inherent) filtration equivalent to 2mm / 0.08inch Al*

The values indicated in the table above can vary from one generator to another. It is the responsibility of each user to calibrate his/her doses before use.

If an image is over or under-exposed, it can be corrected afterwards with the imaging software (contrast, brightness, etc.) to improve its visualisation.

The table below allows you to note the exposure times specific to your generator:

Description	Adult	Child
Lower incisor / canine		
Lower premolar		
Lower molar		
Upper incisor / canine		
Upper premolar		
Upper molar		

5 Hygiene and maintenance

5.1 Hygiene and disinfection

5.1.1 Box

The box does not require any particular maintenance, it should be cleaned using a cloth and non-abrasive detergents.

5.1.2 Sensor

To avoid cross-contamination between patients during use, it is necessary to protect the sensor with hygienic single-use protective sheaths (FDA cleared for the USA, CE marked for Europe). Some hygienic protective sheaths suited for your region are provided with each system.

Before each use on a patient, the used sheath should be thrown away and the sensor disinfected applying a high level disinfection procedure (see “5.2 Recommended disinfection procedure”). A new protective sheath is applied to the sensor for each new patient. We recommend the disposal of the hygienic protective sheaths with the biologically hazardous waste of your practice.

Validated protections for North America: BANTA HEALTHCARE or TIDI PRODUCTS X-ray sensor sheaths, STERI-SHIELD PRODUCTS RS barriers.

Do not pull on the cable when removing the used protective sheath.

5.1.3 Cables

The cable can be cleaned with caution by using a disinfecting wipe. Hold the sensor with one hand and, with the other hand, apply a disinfecting wipe from the side of the sensor along the first 20cm / 8inch of the cable without pulling on the cable; subsequently clean the remainder of the cable in segments of 20-30cm / 8-12inch with as little pinching of the cable as possible, the wipe should slide without applying force.

5.1.4 Positioners

The positioners provided with the system should be covered by the hygienic protective sheath together with the sensor.

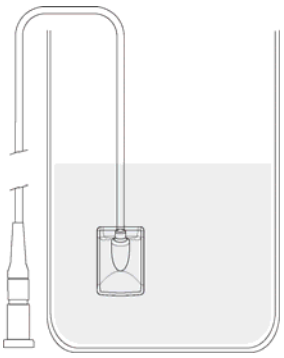
Do not pull on the cable when removing the sensor from the positioner.

They should be cleaned and disinfected according to the same procedure as for the sensor (see “5.2 Recommended disinfection procedure”). They can be sterilised, either in an autoclave (classic steam-sterilizer, distilled water, 134°C / 273°F, 3bar, 4min) or using cold sterilisation (see product instructions). They withstand a maximal temperature of 145°C / 293°F.

A defective positioner can be thrown away with the regular waste.

5.2 Recommended disinfection procedure

Remove the hygienic protective sheath (dispose of it appropriately with the contaminated waste). Vigorously wipe down the sensor to remove any visible residues. If necessary rinse with copious amounts of water. Then place the sensor in the disinfecting agent.



Only immerse the sensor and the beginning of the cable in the disinfectant for 15min, never immerse the connector of the sensor or the connection box in the liquid.

Then rinse thoroughly the sensor with copious amounts of fresh water.

Do not put the sensor in a sterilizer or an autoclave, the high temperature and excessive high pressure will seriously damage the electronics of the sensor.

Do not clean the sensor with inappropriate instruments (knife…).

If the sensor is not being used immediately upon rinsing, as in the case of allowing it to air-dry overnight at the end of a working day, it should be rinsed with sterile water.

When the sensor is not being used and to protect it from any damage, it is recommended to store it in its protective case or to hang it in the sensor wall support.

5.2.1 Recommended disinfectants for North-America

The sensor being sealed watertight and to minimize the potential for device-associated infections, the device shall be disinfected with an FDA-cleared high level disinfection agent following the instructions of the manufacturer for use, storage, handling and warning.

The following disinfectant agent has been validated with the sensor: CIDEX OPA solution (0.55% Ortho-phthalaldehyde solution). The maximum soaking period is 24 hours.

5.2.2 Recommended disinfectants outside North-America

The following disinfectants are compatible with the sensor:

- 2% Glutaraldehydes (maximum immersion time of 24 hours)
- 2% Sodium Hypochlorite (maximum immersion time of 24 hours)
- Ethyl alcohol (maximum immersion time of 24 hours)
- CIDEX

Even when using protective sheaths, the sensor should be disinfected each evening. Immerse the sensor in cold sterilisation fluid in accordance with the instructions of the manufacturer after having cleaned it from all residues. Never leave the sensor immersed for longer than necessary.

5.3 Maintenance

5.3.1 Computer data-protection

Your patient and image database must be backed-up regularly to be able to recuperate them if needed (in case of hard disk or computer problems). Ask the advice of your IT specialist with regard to the backup system that is best suited to your computer configuration (external or removable hard disk, Zip or Jaz system, CD-ROM or DVD writer, etc.). Test and store the copies in a safe place.

6 Troubleshooting

If an error occurs during operation, check the different items in this troubleshooting guide. If you cannot resolve your problem please contact your distributor.

6.1 General

Symptom	Cause / Solution
The kit does not power up (the green light does not light up) or it does not acquire images.	• Check that the active surface of the sensor is directed towards the X-ray generator and is positioned correctly in the field of the X-ray beam. • Check that the kit is correctly configured in the imaging software and that the drivers are correctly installed. • Check that the green light on the box is on and that the sensor toolbar is green; if this is not the case reactivate the box by pushing on the button. • Check that the USB cable is connected correctly to the box and to the computer, and that the computer is switched on. If you use a USB hub, check its connections and make sure it is powered on. • Check that the sensor is connected correctly to the box. • Check that the generator is emitting X-rays (with another sensor or with conventional film).
The red light of the box lights up.	• An error has occurred, disconnect the USB cable and wait a few seconds before reconnecting it.

6.2 Image quality

Symptom	Cause / Solution
The images are cut off, e.g.: 	The sensor is badly positioned with regard to the X-ray beam. • Reposition the sensor, making sure it is well within the field of the X-ray beam. • Use the positioners provided with the sensor for optimal positioning.
The images are too light, e.g.: *Film alike mode* *Auto contrast mode*	• The image is under-exposed, the X-ray dose is too low; increase the X-ray dose on the generator. The percentage that is displayed in the image indicate the exposure level: o 0 to 80% - under-exposed image o 80 to 120% - correctly exposed image o 120 to 200% - over-exposed image • Check the dose emitted by the X-ray generator, due to age the dose can be insufficient. Have the generator checked by a technician when in doubt. • The generator is positioned too far from the patient with regard to the selected dose. • Check the parameters of your monitor (contrast and brightness) and avoid reflections on the screen.
The images are too dark, e.g.: 	• The image is over-exposed, the X-ray dose is too high; reduce the X-ray dose on the generator. The percentage that is displayed in the image indicate the exposure level: o 0 to 80% - under-exposed image o 80 to 120% - correctly exposed image o 120 to 200% - over-exposed image • Check the parameters of your monitor (contrast and brightness) and avoid reflections on the screen.
Grey levels seem to be missing in the image (flat areas of grey appear).	• Check the quality and parameters of the monitor. • Check the connection of the cable of the screen at the side of the graphics card and the monitor. • Check the screen configuration under Windows (screen configuration panel, it must display colours in at least 24bits.
The image is blurred.	Re-acquire the image: • The patient has moved during the exposure. • The generator head was not stabilised and has moved.

7 Specifications

Krystal-X size 1 sensor	
External dimensions size 1 sensor	38,9 x 26,5 x 7,4mm / 1.5 x 1.0 x 0.3inch
CCD matrix size 1 sensor • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 30 x 20mm (600mm^2) / 1.2 x 0.8inch (0.9inch^2) 1500 x 1000pixels 20 x 20µm
Krystal-X size 2 sensor	
External dimensions size 2 sensor	42,7 x 28,5 x 7,4mm / 1.7 x 1.1 x 0.3inch
CCD matrix size 2 sensor • Sensitive area in size • Sensitive area in pixels • Pixel dimensions	 34 x 24mm (816mm^2) / 1.3 x 0.9inch (1.3inch^2) 1790 x 1260pixels 19 x 19µm
Technical specifications (size 1 and 2 sensors)	
Maximum external dimensions of connection box	18,6 x 8,4 x 2,4cm / 7.3 x 3.3 x 0.9inch
Length sensor cable (in polyurethane)	80cm or 2,95m / 2.6ft or 9.7ft
Grey levels	12bits (4096 grey levels)
Connection	USB standard: USB 2.0 High-Speed (480Mbit/s) and USB 1.1 Full-Speed (11Mbit/s)
Consumption kit	2W
Input voltage connection box Input current connection box	5V (through USB connection) 0,4A
Operating temperature	+10°C to +40°C / 50°F to 104°F
Lifespan CCD	Min. 100.000 cycles
Standards	
Sealing standard sensor	IPX 7
Conformity to standards	NF EN/CEI60601-1 NF EN/CEI60601-1-1 NF EN/CEI60601-1-2

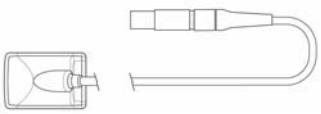
8 Optional kits and accessories

8.1 Optional kits

The optional kits allow you to add a sensor or box to your kit to evolve according to your needs. Each optional kit is supplied with its accessories.

Optional connection box kit with its accessories, compatible with Krystal-X size 1 and 2 sensors

Contact your distributor



Optional Krystal-X size 1 or 2 sensor kit with its accessories

Contact your distributor

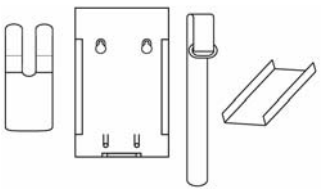
8.2 Accessories

Refill packs of 10 positionners:

D0RT1ANGUBW	Size 1 bitewing
D0RT1ANGUZE	Size 1 endo
D0RT1ANGUZP	Size 1 posterior
D0RT1ANGUZPA	Size 1 peri-apical
D0RT2ANGUBW	Size 2 bitewing
D0RT2ANGUZE	Size 2 endo
D0RT2ANGUZP	Size 2 posterior
D0RT2ANGUZPA	Size 2 peri-apical

Hygienic single-use disposable protection sleeves (for size 1 and 2 sensors)

D0PROTECCAPXL Bag of 20 pieces



Supports and adaptors:

D0SUPCAP730	Sensor wall support
D1KSPKW	Box wall support (with strap and screws)
D0SUPKW	Box wall support
D0RSANGKW	Strap (3 pieces)
D0ADAPTW/2V1	Box adaptor size 2 > 1

USB 2.0 cable

C0CABUSB2-3 3m / 9.8ft cable